SUPPORT FOR THE AMENDMENTS

Newly added Claims 29-38 are supported by the specification at pages 2-17 and by original Claims 1-20. No new matter is believed to have been added to this application by these amendments.

REMARKS

Claims 29-38 are pending, upon entry of the amendment submitted above. Favorable reconsideration is respectfully requested.

The present invention relates to a mouse suitable as a model for atopic dermatitis, wherein the mouse is a NC/Nga mouse which has been impregnated with a mite extract under a specific pathogen free environment, such that the animal displays allergy at least one symptom of atopic dermatitis caused by the mite extract. See Claim 29.

The present invention also relates to a method of producing the mouse by maintaining a NC/Nga mouse in a Specific Pathogen Free environment and impregnating the mouse with the mite extract. See Claim 35.

The present invention additionally relates to a method of screening for an agent for effectiveness against an allergic disorder. See Claim 37.

The rejection under 35 U.S.C. §103(a) over Morita et al. in view of Yasue et al. is respectfully traversed. These references fail to suggest the claimed mouse or the method of making the mouse.

As recognized by the Examiner, Morita et al. describe incubating mice with live fur mites. Therefore, the reference fails to describe administering an extract of an antigen to the mice. In addition, Morita et al. fails to describe using specific pathogen free (SPF) conditions to prepare the mice. This is because live mites were used.

Yasue et al. has nothing to due with producing a mouse suitable as a model for atopic dermatitis. This reference is a study on the effect of recombinant Der f 2 on mice immunized with mite extract (see the Abstract).

There is no motivation from Yasue et al. to modify the procedure described in Morita et al. to use a mite extract instead of live fur mites and to use Specific Pathogen Free (SPF) conditions. The fact that the mice used by Morita et al. prior to their treatment with a mite extract as described in the reference were bred under SPF conditions does not suggest the claimed invention. In fact, Morita et al. actually teach away from the claimed mouse and the method for making the same. In Morita et al., the starting mouse, was bred under SPF conditions, but when it was treated to induce atopic dermatitis via incubation with the live fur mites, the mice were not kept under SPF conditions.

There is no reason to substitute a mite extract for the mites used in Morita et al. That reference teaches that live fur mites can be used to induce atopic dermatitis. There is no basis from either Morita et al. or Yasue et al. that a mite extract could be used to produce a mice suitable as a model for atopic dermatitis. In Morita et al., live mites are used to produce the mice. Yasue et al. do not produce mice which are suitable as a model for atopic dermatitis. Rather, the mice produced therein were used to study the effect of recombinant Der f 2. Specifically, there is no reasonable expectation from these references that using a mite extract will produce a mouse which displays at least one symptom of atopic dermatitis, as explicitly recited in Claim 29. Accordingly, Morita et al. and Yasue et al., taken in combination, fail to suggest the claimed mouse and the method of making the same.

The Examiner has provided no evidence that one of ordinary skill in the art would be motivated to substitute mite extract for live mites. Several advantages are asserted in the Official Action dated June 18, 2002 in support of such an argument, but no evidence to

support those assertions has been provided. For example, the Examiner argues that it would have been obvious to substitute mice extract injection for live mites based on the successful use of mite extracts to generate an allergic response in mice based on the teaching of Yasue et al. However, the Examiner has not substantiated this argument with any evidence whatsoever that there was a reasonable expectation of success that in so doing mice suitable as a model for atopic dermatitis could be obtained. Accordingly, the Office has failed to establish a prima facie case of obviousness over these references.

Hiroi et al. describe the effect of FK506 ointment on spontaneous dermatitis in NC/Nga mice (see the Abstract). This reference does not describe producing mice suitable for an animal model for atopic dermatitis. Accordingly, the claims are not obvious over the combination of Hiroi et al. with Morita et al. and Yasue et al.

Moreover, the claimed mouse has several advantages as compared to the mouse described by Morita et al.

(1) The claimed mouse can be used in a screening directory. When live mites are used , it is necessary to remove the mites and their eggs by using, for example, acaricide (e.g., ivermectine; see page 38 of Morita et al.)

(2) The claimed mouse eliminates all environmental factors other than mite allergen.

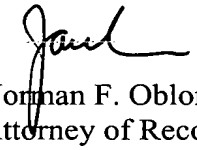
(3) The claimed mouse is readily prepared and has a wide range of applications. Thus, in order to prepare a mouse model for atopic dermatitis, what was necessary was just to inject the suitable skin of the mouse with an extract of the allergen. If one injects the ear of the mouse with the extract, it is very easy to use the screening because the effect of the drug can be assessed quantitatively by measuring the sickness of the ear.

Based on the foregoing, the claimed mouse and methods of making and use are not obvious over the combination of Morita et al., Yasue et al., and Hiroi et al. Withdrawal of these grounds of rejection is respectfully requested.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Norman F. Oblon
Attorney of Record
Registration No. 24,618

James J. Kelly, Ph.D.
Registration No. 41,504

22850
Tel. (703) 413-3000
Fax. (703) 413-2220
(OSMMN 11/98)

ATTORNEY DOCKET NO.: 0018-1098-0
SERIAL NO.: 09/548,290

MARKED-UP COPY

Serial No.: 09/548,290
Amendment Filed On: Herewith

IN THE CLAIMS

Claims 21-28 (Canceled)

Claims 29-38 (New)